UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

TULSA FIREFIGHTERS HEALTH AND WELFARE TRUST, on behalf of itself and all others similarly situated, *Plaintiff*, v. ALLERGAN PLC, IMPAX LABORATORIES, INC., THE LANNETT COMPANY, INC., MYLAN INC., PAR PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES CO., and WEST-WARD PHARMACEUTICAL CORP., *Defendants*.	No. CLASS ACTION JURY TRIAL DEMANDED

1. Plaintiff Tulsa Firefighters Health and Welfare Trust, on behalf of itself and all others similarly situated, brings this class action for claims under federal and state antitrust laws to recover damages and obtain injunctive and equitable relief for the substantial injuries it and others similarly situated have sustained against Defendants Allergan plc, Impax Laboratories, Inc., The Lannett Company, Inc., Mylan Inc., Par Pharmaceuticals, Inc., Sun Pharmaceutical Industries Co., and West-Ward Pharmaceutical Corp. arising from their conspiracy to fix, raise, maintain, and stabilize the prices of certain doxycycline products and digoxin tablets, 0.125 mg and 0.25 mg ("digoxin tablets"), in the United States and allocate markets and customers for those products. Plaintiff's allegations are made on personal knowledge as to Plaintiff and Plaintiff's own acts and upon information and belief as to all other matters.

NATURE OF THE ACTION

2. Both doxycycline and digoxin are commonly prescribed medications. Doxycycline is a broad-spectrum antibiotic used for the treatment of a variety of bacterial

infections, including bacterial pneumonia, acne, chlamydia, Lyme disease (early stages), cholera, and syphilis. Digoxin is prescribed for the treatment of atrial fibrillation and other cardiac ailments. Their common use has led to both drugs being designated as "essential medicines" by the World Health Organization.[1]

3. Significantly, neither drug is new: doxycycline was developed in the mid-20th century and was on the market by December 1967; and digoxin is even older, with the therapeutic properties of the drug having been known since the late 18th century. Neither drug compound is protected by any patents.

4. Generic versions of both drugs have been on the market for at least two decades and, for much of that time, have cost only pennies per tablet or capsule. This is because the presence of generic drugs usually results in vigorous price competition, benefiting consumers and third-party payors through lower prices.

5. Recently, however, both drugs have experienced unprecedented increases in prices. Specifically, since October 2012, the price of doxycycline has increased ***over 8,000%***. And, since October 2013, the price of digoxin tablets has increased ***over 800%***.

6. These price hikes were not the result of competitive market forces; instead, they were the product of Defendants' conspiracy to fix, raise, maintain, and stabilize the prices of, as well as allocate customers and markets for, these products. Defendants orchestrated their conspiracy through secret communications and meetings, both in private and at public events, such as trade association meetings held by the Generic Pharmaceutical Association. Oligopolistic conditions—*e.g.*, the low numbers of competitors and barriers to entry in the markets for

[1] World Health Org., WHO Model List of Essential Medicines (Apr. 2015), at 8, 6, 17, 27, 29, http://www.who.int/selection_medicines/committees/expert/20/EML_2015_FINAL_amended_AUG2015.pdf?ua=1.

doxycycline and digoxin tablets—facilitated Defendants' anticompetitive actions and have allowed them to sustain their unlawful supracompetitive pricing to the present.

7. These two drugs are just the tip of the iceberg. The exorbitant price increases for doxycycline and digoxin tablets mirror a series of large price hikes observed across a number of other generic drugs manufactured by these Defendants and several other companies. Defendants' price increases have grabbed the attention of the government enforcers, members of Congress, the press, and drug purchasers. The Department of Justice ("DOJ") and the Connecticut Attorney General's Office ("CTAG") issued subpoenas to Defendants Impax, Lannett, and Par seeking documents and testimony concerning the pricing of digoxin tablets. Defendants Allergan, Lannett, Mylan, and Par received similar subpoenas in connection with their pricing of doxycycline. The DOJ's subpoenas to these companies arise from a grand jury proceeding in the Eastern District of Pennsylvania.

8. In addition to DOJ's and CTAG's investigations, members of Congress have written letters to each Defendant, requesting information concerning their sales of doxycycline and digoxin. Members of Congress also requested information from Defendants and other generic drug manufacturers regarding other generic drugs that have similarly undergone significant price increases over the past few years, including: albuterol sulfate, glycopyrrolate, divalproex sodium ER, pravastatin sodium, neostigimine methylsulfate, and benazepril/hydrochlorothiazide.

9. As a result of Defendants' scheme to fix, raise, maintain, and stabilize the prices of doxycycline and digoxin tablets, consumers and third-party payors paid, and continue to pay, supracompetitive prices for doxycycline and digoxin tablets.

10. Plaintiff seeks to certify two classes. The first class (the "Injunctive Class") is composed of all individuals and entities in the United States or its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for: (i) doxycycline, in any form, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2012 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased (the "Doxycycline Class Period"); or (ii) digoxin tablets, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2013 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased (the "Digoxin Class Period").

11. The second class (the "Damages Class") is composed of all individuals and entities who, in Alabama, Arizona, California, Florida, Hawaii, Iowa, Kansas, Massachusetts, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia, indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for: (i) doxycycline, in any form, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2012 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased; or (2) digoxin tablets, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2013 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.

JURISDICTION AND VENUE

12. Plaintiff brings this action under Section 16 of the Clayton Act, 15 U.S.C. §26, to obtain injunctive relief and costs of suit, including attorneys' fees, against Defendants for the injuries that Plaintiff and the other members of the Class have suffered from Defendants' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 16 of the Clayton Act, 15 U.S.C. § 26, because this action arises under the federal antitrust laws. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

14. This Court also has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds $5,000,000 and at least one member of the Damages Class is a citizen of a state different from that of one of Defendants.

15. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), and (d) and Section 12 of the Clayton Act, 15 U.S.C. § 22, because Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

16. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

17. Defendants sold and shipped doxycycline and digoxin tablets in a continuous and uninterrupted flow of interstate commerce. The conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate and intrastate commerce.

18. Each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their conspiracy.

THE PARTIES

A. Plaintiff

19. Plaintiff Tulsa Firefighters Health and Welfare Trust ("**Tulsa Firefighters**") is an employee welfare benefits fund with its principal place of business at 1350 South Boulder Avenue, Tulsa, Oklahoma, 74119. Tulsa Firefighters provides health and welfare benefits to active and retired members who live in Kansas, Oklahoma, and Texas, among other states. During the Doxycycline and Digoxin Class Periods, Tulsa Firefighters purchased and paid for some or all of the purchase price for one or more of the doxycycline and digoxin products at issue in this Complaint, thereby suffering injury to its business and property. Tulsa Firefighters paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets and customers.

B. Defendants

20. Defendant Allergan plc ("**Allergan**") is an Irish corporation with its principal place of business at Coolock, Dublin D17 E400, Ireland. Allergan develops, manufactures, markets, and distributes branded and generic pharmaceutical products. Allergan also maintains U.S. offices at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. Allergan was formed through the acquisition of Allergan Inc. by Actavis plc ("Actavis") on May 17, 2015. Upon completion of the acquisition, Actavis was renamed Allergan. During the Doxycycline Class Period, Allergan manufactured and sold generic doxycycline in the United States.

21. Defendant Impax Laboratories, Inc. ("**Impax**") is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544. Impax is a technology-based specialty pharmaceutical company. During the Digoxin Class Period, Impax manufactured and sold generic digoxin tablets in the United States through its Global Pharmaceuticals division.

22. Defendant The Lannett Company, Inc. ("**Lannett**") is a Delaware corporation with its principal place of business at 9000 State Road, Philadelphia, PA, 19136. Lannett develops, manufactures, markets, and distributes generic versions of brand pharmaceutical products. During the Digoxin Class Period, Lannett distributed and sold generic digoxin tablets, which were manufactured by Jerome Stevens Pharmaceuticals Inc. ("Jerome Stevens"), in the United States.

23. Defendant Mylan, Inc. ("**Mylan**") is a Pennsylvania corporation with its principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317. Mylan manufactures, markets, and sells branded and generic pharmaceutical products in the United States. During the Doxycycline and Digoxin Class Periods, Mylan manufactured and sold generic doxycycline and digoxin tablets in the United States.

24. Defendant Par Pharmaceuticals, Inc. ("**Par**") is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York, 10977. Par manufactures, markets, and sells generic pharmaceutical products in the United States. In May 2015, Endo announced that it was acquiring Par for $8.05 billion. The merger was completed in September 2015. During the Doxycycline and Digoxin Class Periods, Par manufactured and sold generic digoxin tablets and generic doxycycline in the United States.

25. Defendant Sun Pharmaceutical Industries Ltd. ("**Sun**") is an Indian corporation with U.S. offices located at 270 Prospect Plains Road, Cranbury, New Jersey, 08512. The term "Sun" includes its subsidiaries, Caraco Pharmaceutical Laboratories Ltd. ("Caraco"), which became a wholly-owned subsidiary in 2010, and URL Pharma ("URL"), which became a subsidiary of Caraco in 2013. Sun manufactures, markets, and sells branded and generic pharmaceutical products in the United States. During the Doxycycline and Digoxin Class Periods, Sun manufactured and sold generic digoxin tablets and generic doxycycline in the United States.

26. Defendant West-Ward Pharmaceutical Corp. ("**West-Ward**") is a New Jersey corporation with its principal place of business at 401 Industrial Way West, Eatontown, New Jersey, 07724. West-Ward is a subsidiary of Hikma International Pharmaceuticals PLC ("Hikma"), a Jordanian pharmaceutical company. West-Ward manufactures, markets, and sells various generic pharmaceutical products in the United States. During the Doxycycline and Digoxin Class Periods, West-Ward manufactured and sold generic digoxin tablets and generic doxycycline in the United States.

27. Defendants Allergan, Impax, Lannett, Mylan, Par, Sun, and West-Ward are referred to collectively as "**Defendants**."

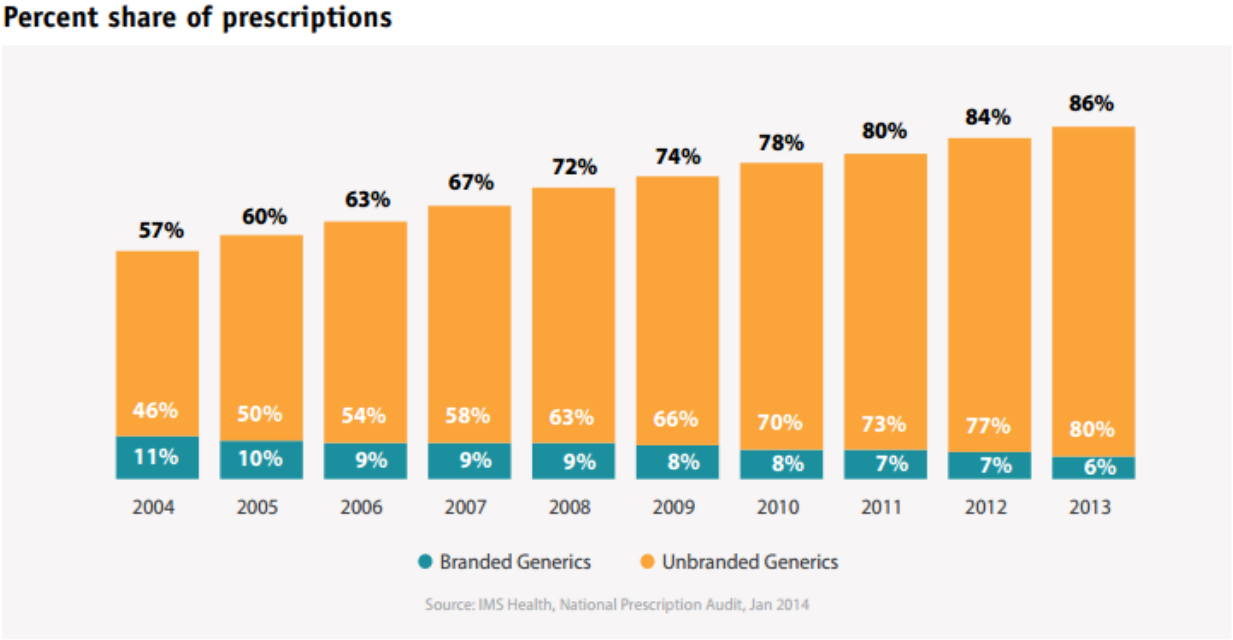
28. Various other entities and individuals unknown to Plaintiff at this time participated as co-conspirators in the acts complained of, and performed acts and made statements that aided and abetted and were in furtherance of the unlawful conduct alleged herein.

GENERIC DRUGS REDUCE PRESCRIPTION DRUG COSTS TO PATIENTS AND THIRD-PARTY PAYORS

29. When generic versions of a branded drug—whether a generic manufactured and sold by an independent generic manufacturer or an "authorized generic," or "branded generic,"

sold pursuant to an agreement with the branded manufacturer—enter the market, absent anticompetitive activity, the resulting competition causes rapid erosions in the prices of the drug.

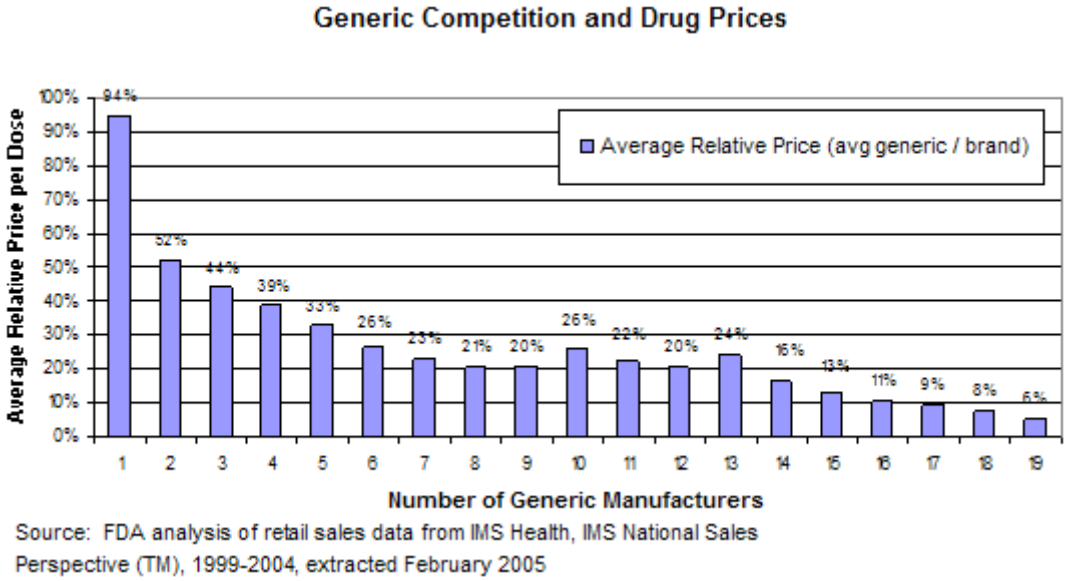
30. Empirical studies have shown that within a year of generic entry, generics typically will have obtained about 90% of the market, *i.e.*, pharmacists will fill 90 of every 100 prescriptions with a generic. Indeed, according to IMS Health data, generic drugs as a whole have increased the share of total prescriptions steadily since 2004, and as of 2013, account for 86% of all drugs dispensed in the United States.[2]



31. The ubiquity of generic drugs ultimately leads to lower prices for consumers and third-party payors. Indeed, in a competitive market, each successive generic product that enters the market lowers the prices of all similar generic products because each entry increases competition for sales and market share, thereby inducing all generic manufacturers to lower their

[2] IMS Institute for Healthcare Informatics, Medicine use and shifting costs of healthcare: A review of the use of medicines in the United States in 2013 (Apr. 2014), at 51, http://www.plannedparenthoodadvocate.org/2014/IIHI_US_Use_of_Meds_for_2013.pdf.

prices in response to the new competitor. A Food and Drug Administration ("FDA") study demonstrates this effect in the following chart:[3]



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

32. A Federal Trade Commission study confirmed the FDA's analyses, finding that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[4]

33. Thus, generic competition to even a single brand drug can provide potentially billions of dollars in savings to consumers, pharmacies, and other drug purchasers, as well as to private health insurers, health and welfare funds, and state Medicaid programs, which reimburse the cost of drug purchases by covered individuals. Indeed, one study found that the use of generic medicines saved the U.S. healthcare system $254 billion in 2014 alone, and $1.68 trillion between 2005 and 2014.[5]

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[3] FDA, Generic Competition and Drug Prices, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

[4] FTC Staff Study, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at* http://emmanuelcombe.org/delay.pdf.

[5] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

34. These consumer welfare-enhancing attributes of generic drug competition were bolstered by the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act." The Hatch-Waxman Act simplifies the regulatory hurdles that generic drug manufacturers have to clear prior to marketing and selling generic drugs. Instead of filing a lengthy and costly New Drug Application ("NDA"), the Hatch-Waxman Act allows generic drug manufacturers to obtain FDA approval in an expedited fashion through the filing of an Abbreviated New Drug Application ("ANDA").

35. If an ANDA applicant shows that the generic drug is bioequivalent to the brand drug, then the ANDA applicant may rely on scientific and other data compiled in the brand drug's NDA, including safety and efficacy data. The ability to rely on the scientific data published in the referenced brand drug's NDA obviates the need for duplicative and expensive experimentation and clinical trials. The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements under the Hatch-Waxman Act.

36. In connection with the approval of a generic drug, the FDA will assign a "Therapeutic Equivalence Code" ranging from "AA" to "BX." An "AB" rating signifies that the approved generic product is therapeutically equivalent to its branded counterpart. An AB rating is significant because under state generic drug substitution laws, pharmacists are permitted—and in many cases, must—substitute the branded product for its cheaper generic counterpart. This inures to the financial benefit of consumers and third-party payors.

37. In sum, the streamlined approval process under the Hatch-Waxman Act makes it easier for generic drug manufacturers to bring competing and cheaper generic products to market.

FACTUAL BACKGROUND REGARDING DOXYCYCLINE AND DIGOXIN

A. Background on Doxycycline and Digoxin

38. Doxycycline is a broad-spectrum antibiotic within the tetracycline class. Doxycycline is indicated to treat a variety of bacterial infections including: bacterial pneumonia, acne, chlamydia, Lyme disease (early stages), cholera, and syphilis. Doxycycline was discovered in 1967.

39. Doxycycline comes in two common varieties: doxycycline hyclate and doxycycline monohydrate. Their chemical formulas are similar—each containing the base $C_{22}H_{24}N_2O_8$—and both are synthetically derived from oxytetracycline. Both are also indicated to treat a broad spectrum of bacterial infections.

40. Digoxin is a drug used for the treatment of atrial fibrillation (heart arrhythmia) and heart failure. Digoxin helps slow abnormal heart rhythms and strengthens the heart's contractions. Many elderly patients with cardiac issues are prescribed digoxin. Digoxin is derived from digitalis, an extract of the foxglove plant, which was first described in medical literature by a British doctor in 1785. Annual U.S. sales of digoxin tablets are approximately $44 million.[6]

41. The popularity and effectiveness of doxycycline and digoxin have led the World Health Organization to include both on its list of "essential medicines."

B. Manufacturers of Doxycycline

42. The popularity and effectiveness of doxycycline lead to numerous branded and generic manufacturers creating different versions of the drug.

[6] Press Release, Par Pharmaceuticals Begins Shipment of Generic Lanoxin® (Jan. 6, 2014), http://www.prnewswire.com/news-releases/par-pharmaceutical-begins-shipment-of-generic-lanoxin-240577991.html.

1. Brand Manufacturers of Doxycycline

43. Branded versions of doxycycline are produced by Pfizer Inc., Aqua Pharmaceuticals LLC, and Fougera Pharmaceuticals Inc., among others.

(a) Pfizer developed and manufactured Vibramycin® and Vibra-Tabs®. Vibramycin is a capsule form of doxycycline hyclate. Vibra-Tabs is a tablet form of Vibramycin. Pfizer received FDA approval for Vibramycin (NDA 050007) on December 5, 1967 and received FDA approval for Vibra-Tabs (NDA 050533) on January 15, 1980. Later, Pfizer withdrew Vibra-Tabs from the market. However, the FDA determined that Pfizer's withdrawal of Vibra-Tabs was not for reasons of safety or effectiveness, meaning that all existing generic versions could remain on the market.

(b) Aqua developed and manufactured Monodox®. Monodox is a capsule version of doxycycline monohydrate. Aqua received FDA approval for Monodox (NDA 050641) on December 29, 1989.

(c) PharmaDerm, a division of Fougera, manufactures branded versions of Adoxa®. Adoxa is a version of doxycycline monohydrate that comes in both capsule and tablet form.

2. Generic Manufacturers of Doxycycline

44. Generic drug manufacturers that currently market generic versions of doxycycline in the United States are Allergan, Lannett, Mylan, Par, Sun, and West-Ward.

(a) Allergan manufactures generic versions of Vibramycin, Vibra-Tabs, and Monodox (capsule form). Allergan's generic version of doxycycline first entered the market in 1982.

(b) Lannett manufactures generic versions of Adoxa (tablet form). Lannett launched its generic versions of doxycycline in December 2005.

(c) Mylan manufactures generic versions of Adoxa (capsule and tablet forms) and Vibra-Tabs. Mylan's generic versions of doxycycline first entered the market in 1982.

(d) Par manufactures generic versions of Adoxa and Monodox (both capsule and tablet forms). Par launched its generic versions of Monodox in 2000 and generic versions of Adoxa in December 2005.

(e) Sun manufactures generic versions of Vibramycin, Vibra-Tabs, and Monodox (capsule form). Sun, through its subsidiary Caraco, acquired the rights for doxycycline through its acquisition of URL Pharma, Inc.'s generic business from Takeda Pharmaceutical Company Limited in December 2012.

(f) West-Ward manufactures generic versions of Vibramycin and Vibra-Tabs. West-Ward launched its generic versions of doxycycline in 2003.

3. Reduction in Competition in the Market for Generic Doxycycline Due to Exit of Competitors

45. At one point there were over 20 manufacturers of generic doxycycline.[7] However, over the past decade, the number of generic drug manufacturers producing doxycycline has steadily dropped. Major Pharmaceuticals, Teva Pharmaceuticals, and West-Ward were among the generic manufacturers that discontinued certain doxycycline product lines. Major Pharmaceuticals' and Teva Pharmaceuticals' discontinuations occurred in or around February 2013 and May 2013, respectively.[8] West-Ward discontinued one line of doxycycline in or around July 2013.[9]

[7] Steve Myrick, *Cost of Doxycycline Skyrockets*, Vineyard Gazette (Sept. 24, 2015), https://vineyardgazette.com/news/2015/09/24/cost-doxycycline-skyrockets.

[8] http://www.ashp.org/menu/DrugShortages/CurrentShortages/bulletin.aspx?id=977.

[9] https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c4aae81f-0219-450f-aa60-953964f74172.

46. This reduction in the number of generic manufacturers increased concentration in the doxycycline market, facilitating price coordination and Defendants' conspiracy to fix, raise, maintain, and stabilize prices for doxycycline.

C. The Manufacturers of Digoxin Tablets

47. Prior to July 26, 2002, many drug manufacturers produced and sold digoxin tablets. Because digoxin is a drug that was available before the passage of the 1938 Federal Food, Drug, and Cosmetic Act, digoxin was marketed outside of the normal NDA-ANDA regulatory process. As a result, numerous manufacturers produced and marketed digoxin tablets, subject only to the requirements of the former 21 C.F.R. § 310.500, "which established conditions for marketing digoxin products for oral use (tablets and elixir)."[10] However, subsequent FDA rule-making, effective on July 26, 2002, required manufacturers of digoxin tablets to submit NDAs or ANDAs for FDA approval.

1. Brand Manufacturer of Digoxin Tablets

48. On September 30, 1993, GlaxoSmithKline ("GSK") filed an NDA for the approval digoxin tablets, under the brand name Lanoxin®. GSK's NDA sought FDA approval of the following strengths: 0.0625 mg, 0.125 mg, 0.187 mg, 0.25 mg, 0.375 mg, and 0.5 mg.

49. However, during its NDA approval process, GSK ultimately decided not to pursue marketing of the 0.0625 mg, 0.187 mg, 0.375 mg, and 0.5 mg strengths. As a result, in its September 30, 1997 approval letter, the FDA only approved the manufacturing and sale of the 0.125 mg and 0.25 mg tablets. Swiss drug manufacturer Covis Pharmaceuticals, Inc. ("Covis") purchased the rights to Lanoxin and several other GSK branded drugs on December 22, 2011.

[10] 67 Fed. Reg. 42992-97 (Jun. 26, 2002), http://www.fda.gov/OHRMS/DOCKETS/98fr/062602b.htm.

On April 1, 2015, Covis and its assets—including its rights to Lanoxin—were acquired by Concordia Healthcare Corp. ("Concordia") in an all-cash deal.

2. Generic Manufacturers of Digoxin Tablets

50. Because GSK's Lanoxin was not protected by any patents, generic competitors were able to enter the market shortly after GSK began marketing Lanoxin. Indeed, because digoxin was not a new chemical entity, GSK was only entitled to three years of brand exclusivity—*i.e.*, after three years, the FDA could approve generic manufacturers' ANDAs for generic versions of Lanoxin.

51. One of the first generics to file an ANDA in connection with generic Lanoxin was Amide Pharmaceuticals, Inc. ("Amide"). Amide filed ANDA 040282 on October 21, 1997, seeking approval for digoxin tablets. The FDA granted final approval on December 23, 1999. Amide and Mylan—through Mylan's wholly-owned subsidiary Bertek Pharmaceuticals—entered into a distribution agreement, whereby Mylan distributed Amide's approved digoxin tablets under the name "Digitek."

52. The next generic to file an ANDA for generic Lanoxin was Jerome Stevens. Jerome Stevens filed ANDA 76268 on October 29, 2001, seeking approval for digoxin tablets. The FDA granted final approval on July 26, 2002. In March 2004, Jerome Stevens entered into a 10-year exclusive distribution agreement with Lannett, whereby Lannett became the exclusive seller of Jerome Stevens' digoxin tablets. In exchange, Jerome Stevens received four million shares of Lannett's common stock. In August 2013, this exclusive distribution deal was renewed for another five years.

53. At least four other generic manufacturers entered the market for digoxin tablets after Lannett, including:

(a) Sun, which received approval for ANDA 076363 on January 31, 2003;

(b) West-Ward, which received approval for ANDA 077002 on October 30, 2007;

(c) Impax, which received approval for ANDA 078556 on July 20, 2009; and

(d) Par which entered the market on January 16, 2014 as an authorized generic version of Lanoxin.

3. Reduction of Competition in the Market for Generic Digoxin Tablets Due to Exit of Competitors

54. As of 2002, there were eight manufacturers of digoxin tablets. However, in the years since, the number of digoxin tablet manufacturers has steadily decreased. Certain manufacturers have left the digoxin tablet market for business and regulatory reasons. Mylan, which still lists Digitek as one of its "Institutional Products,"[11] stopped selling digoxin tablets, even though it maintains an active ANDA in connection with this product. Its discontinuation of digoxin tablet sales appears to be related to a late-April 2008 recall of digoxin tablets distributed by Mylan because of quality control issues, which resulted in twice the amount of active ingredient to be present in their digoxin tablets. After that recall, Mylan's share of the digoxin tablet market was "wiped out."[12] According to data published by the Centers for Medicare and Medicaid Services ("CMS"), Mylan returned to the digoxin tablet market in or around early 2015.

55. Similarly, Sun experienced manufacturing difficulties around the same time as Mylan. Its subsidiary, Caraco, received a Form 483 and a Warning Letter from the FDA relating

[11] http://www.mylaninstitutional-usproducts.com/MylanInstitutionalProducts/ProductSearch?SearchTerm=DIGITEK%C2%AE%20(digoxin%20tablets,%20USP).

[12] How little-known Lannett may soon become a billion-dollar generic company, PharmaCompass (Sept. 10, 2015), http://www.pharmacompass.com/pharma-news/how-little-known-lannett-may-soon-become-a-billion-dollar-generic-company.

to quality control practices at its Detroit facility. In March 2009, Caraco voluntarily withdrew certain lots of digoxin tablets because of manufacturing issues that resulted in inconsistent levels of the active ingredients being found in the tablets.

56. Because of the issues affecting Mylan and Sun, there were only three generic drug manufacturers producing and selling digoxin tablets during most of the Digoxin Class Period: Impax, Lannett, and West-Ward.

57. Then, on February 3, 2012, the FDA issued a Warning Letter to West-Ward regarding its failure to comply with Current Good Manufacturing Practice ("CGMP") at its Eatontown, New Jersey facility where West-Ward's digoxin tablets are manufactured.[13] The Warning Letter was directed specifically at testing and manufacturing failures relating to digoxin tablets.

58. As a result of the FDA's Warning Letter, West-Ward "voluntarily ceased manufacturing of all product lines" and shuttered operations at its Eatontown facility temporarily in the beginning of 2013.[14] The Eatontown facility was reopened by July 2013, and West-Ward resumed manufacturing digoxin tablets. However, the issues relating to the warning letter were not fully resolved until March 26, 2014, when the FDA sent West-Ward a "close-out" letter.[15]

59. The difficulties faced by Impax's and Lannett's competitors with respect to the manufacturing and sale of digoxin tablets enabled Impax and Lannett to seize control of the market for generic digoxin tablets. According to Lannett's CEO, Arthur Bedrosian, the two companies were the only competitors in that market for a considerable period of time. Once

[13] *See* FDA Warning Letter 12-NWJ-10 (Feb. 3, 2012).

[14] Hikma Annual Report 2013, at 17, http://www.hikma.com/~/media/Files/H/Hikma/Attachments/pdf/reports/financial-reports/annual-report-2013.pdf.

[15] *See* FDA West-Ward Pharmaceutical Corp. Close Out Letter (Mar. 26, 2014).

West-Ward's Eatontown facility reopened in the latter half of 2013, there were still only three generic manufacturers of digoxin tablets. Par's entry in January 2014 with an authorized generic version of Lanoxin increased the total generic manufacturers to four. Mylan's re-entry in early 2015 increased the total generic manufacturers of digoxin tablets to only five.

60. But, as explained below, the increase in the number of competitors has not produced the customary drop in prices; rather, prices have continued to remain at supracompetitive levels as a result of Defendants' unlawful conduct.

DEFENDANTS' WRONGDOING

A. Defendants Conspired to Raise Prices for Doxycycline to Supracompetitive Levels

61. The prices of doxycycline have dramatically increased over the past few years. For example, *The Los Angeles Times* reported that in December 2012, an individual who purchased doxycycline at CVS paid $4.30 for 60 pills. Three months later, in February 2013, the price for the same quantity of doxycycline jumped to $165.[16] Pembroke Consulting, a Philadelphia-based research firm, found that prices of doxycycline hyclate rose ***over 6,350%*** between November 2012 and November 2013.[17]

62. Further evidence of these staggering price increases for doxycycline was presented at a November 20, 2014 congressional hearing. Dr. Stephen Schondelmeyer, Director of the PRIME Institute at the University of Minnesota College of Pharmacy, found that generic doxycycline hyclate prices were generally stable prior to October 2012. Dr. Schondelmeyer tracked Average Wholesale Prices ("AWP"), Wholesale Acquisition Costs ("WAC"), and retail

[16] David Lazarus, *When a drug costs 30 times what it once did*, L.A. Times (Mar. 7, 2013), http://articles.latimes.com/2013/mar/07/business/la-fi-lazarus-20130308.

[17] Victoria Colliver, *Prices soar for some generic drugs*, SFGate (Jan. 1, 2014), http://www.sfgate.com/health/article/Prices-soar-for-some-generic-drugs-5105538.php.

prices for doxycycline hyclate manufactured by West-Ward. West-Ward's AWPs for doxycycline hyclate held steady at around $2.50 per day, from January 2005 to the beginning of October 2012. Retail prices during that period held steady at $0.50 per day. Similarly, WAC held steady at around $0.25 per day during that same period.[18]

63. However, after October 2012, AWP skyrocketed to $11 per day—an increase of nearly ***340%***. Retail prices exhibited a similarly large increase, jumping to $8.50 per day—an increase of nearly ***1,600%***. WAC prices also increased to nearly $9.00 per day—an increase of nearly ***3,500%***.[19]

64. Plaintiff analyzed several sources of pricing data for doxycycline (some of which is subject to a non-disclosure agreement), including data compiled by CMS. Plaintiff analyzed CMS's National Average Drug Acquisition Cost ("NADAC") price data, which compiles weekly and monthly surveys for Medicaid-covered outpatient drugs, including doxycycline. According to CMS, "[t]he NADAC is designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and other-the-counter covered outpatient drugs." [20] The CMS data, depicted below, shows that the price hikes for doxycycline (both the hyclate and monohydrate forms) were generally in lock-step and industry-wide.

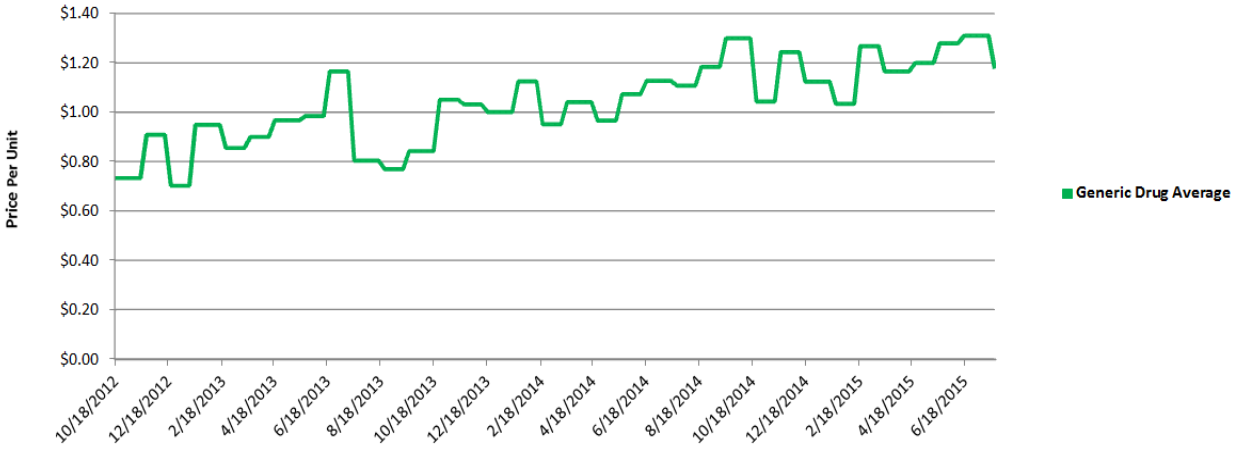
65. The charts below show the average per unit (capsule or tablet) prices of doxycycline hyclate and monohydrate:

[18] Statement of Stephen W. Schondelmeyer, BS Pharm, Senate Hearing on "Why Are Some Generic Drugs Skyrocketing in Price?" at App'x B.7.

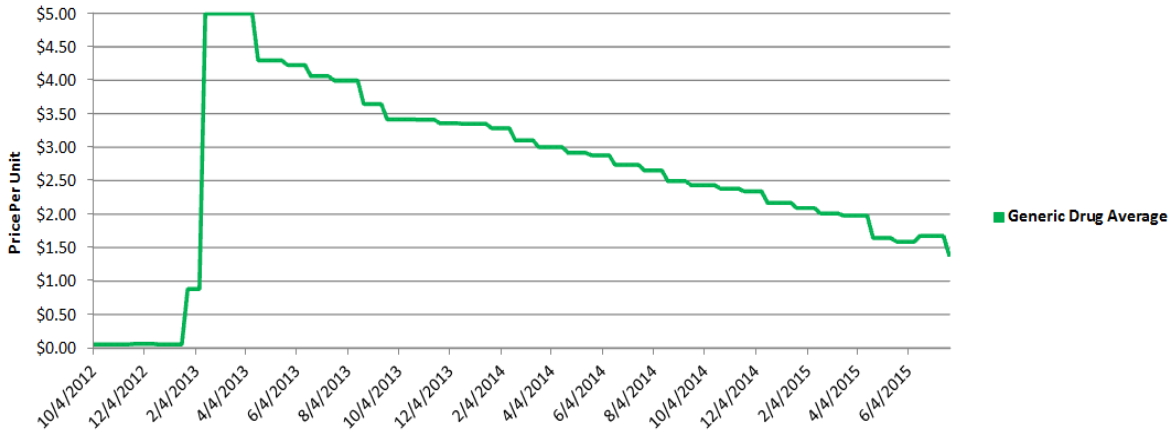
[19] *Id.*

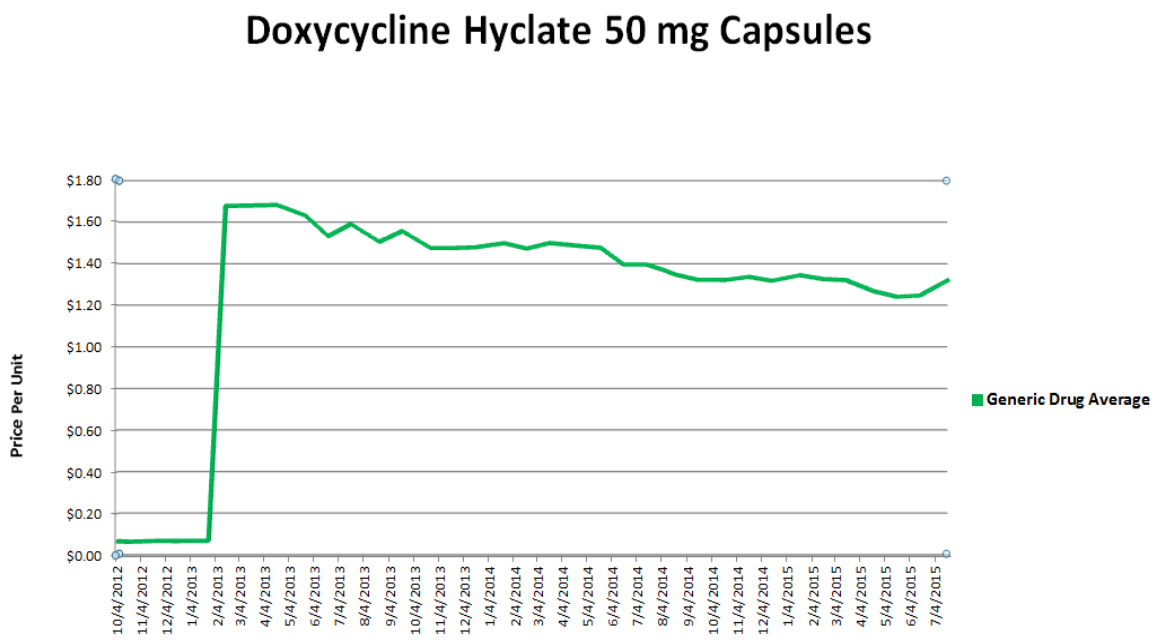
[20] CMS, METHODOLOGY FOR CALCULATING THE NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC) FOR MEDICAID COVERED OUTPATIENT DRUGS, at 5 (Nov. 2013), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf.

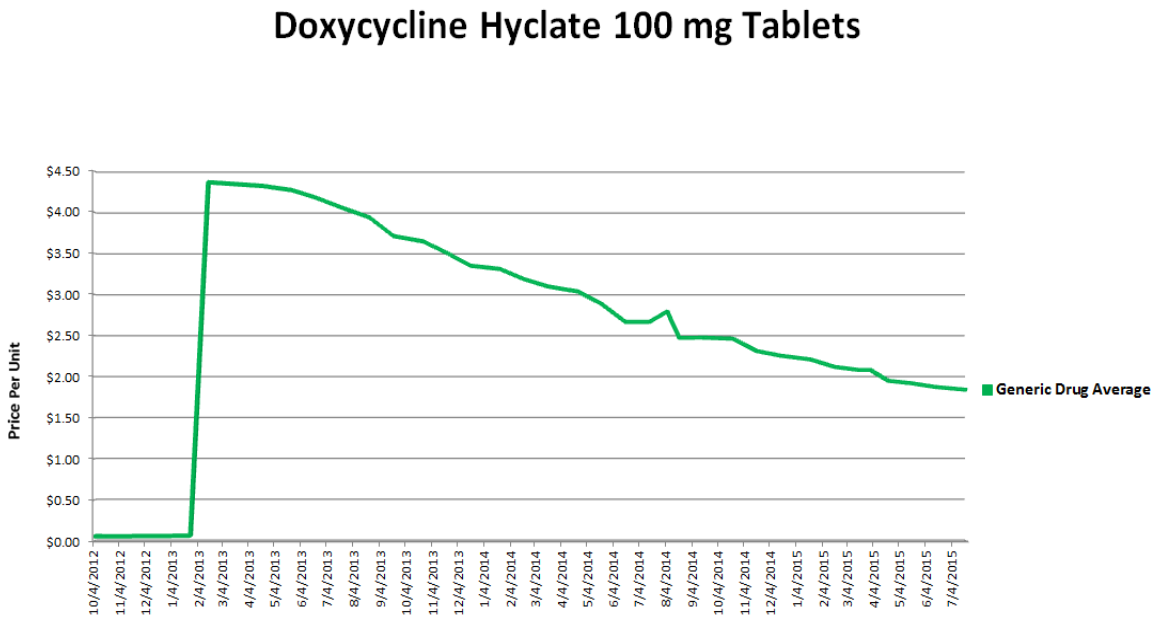
Doxycycline Monohydrate 100 mg Tablets



Doxycycline Hyclate 100 mg Capsules







66. The NADAC data demonstrate that: (1) prices for doxycycline monohydrate, 100 mg tablets (*i.e.*, generic Monodox and Adoxa), have ***increased 78%*** from their October 2012 prices; (2) prices for doxycycline hyclate 100 mg capsules (*i.e.*, generic Vibramycin 100 mg capsules), have ***increased over 2,400%*** from their October 2012 prices; (3) prices for

doxycycline hyclate 50 mg capsules (*i.e.*, generic Vibramycin 50 mg capsules) have ***increased nearly 1,800%*** from their October 2012 prices; and (4) prices for doxycycline hyclate 100 mg tablets (*i.e.*, generic Vibra-Tabs 100 mg tablets) have increased ***over 3,100%*** from their October 2012 prices.

67. These jumps in price for doxycycline were not simply the product of one rogue doxycycline manufacturer. A rogue manufacturer's supracompetitive pricing would have quickly disappeared because other generic doxycycline manufacturers would have taken away that manufacturer's sales and market share with competing lower-priced generic doxycycline products. Rather, these supracompetitive prices were the product of a conspiracy between Defendants to raise, maintain, and stabilize the prices of doxycycline to purchasers in the United States.

68. Defendants' own public statements suggest as much. For example, in commenting on West-Ward's decision to increase the price of doxycycline over 3,500%, Hikma (West-Ward's parent) CEO, Said Darwazah, incredulously stated in an August 2013 interview that West-Ward was "***'forced'*** to raise prices because its competitors raised theirs."[21] Mr. Darwazah's explanation defies economic rationality because an increase in price by competitors did not compel a matching price *rise* by West-Ward; to the contrary, it provided West-Ward an opportunity to maintain lower prices, or even cut them, to gain market share at the expense of its competitors. However, West-Ward did not do so because it was conspiring with the other Defendants to fix and raise the prices of doxycycline.

[21] Alan Katz, *Surprise! Generic-Drug Prices Spike*, Bloomberg Business (Dec. 12, 2013), http://www.bloomberg.com/bw/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise.

69. Defendants' adherence to their price-fixing scheme generated considerable profits. In March 2014, Hikma, West-Ward's parent, announced that revenues from its generic products increased 158% to $268 million, "***reflecting very strong doxycycline sales***."[22]

70. Sun similarly reported in September 2015 and February 2016 investor presentations that one of the "key drivers" of its sales through the period 2012 through 2014 was doxycycline, which it described as a "***low competition product***[]" in the United States—a notable description in light of the large number of competitor products.[23] In 2013, Sun's subsidiary URL "had undertaken price hikes in March" and that as a result of these price increases, Sun estimated that "$60-80 million (of $128 million in total revenue for URL estimated . . . for FY[20]14) to come from [doxycycline], with operating margins in the range of 50-55 per cent."[24] These figures appear to be underestimates: one Credit Suisse analyst found that doxycycline sales accounted for over $210 million in revenues for Sun.[25]

B. Defendants Conspired to Raise Prices for Generic Digoxin Tablets to Supracompetitive Levels

71. The prices of digoxin tablets have also been subject to large-scale increases over the last few years. In July 2014, *The New York Times* reported that digoxin tablet prices soared over the past year and a half, beginning in late-2013—doubling at the manufacturer to wholesale

[22] Press Release, Hikma delivers an excellent performance in 2013 with Group revenue growth of 23% and EPS up 111%; Hikma expects continued growth in 2014 (Mar. 12, 2014), http://www.hikma.com/~/media/Files/H/Hikma/Attachments/pdf/news/corporate/prel-res-pr-12032014.pdf.

[23] Sun Pharma, Creating Lasting Value – Investor Presentation (Feb. 2016), at 47, http://www.sunpharma.com/sites/all/themes/sunpharma/images/annual/IR%20Presentation%20Feb%202016.pdf.

[24] Ujjval Jauhari, *Sun Pharma's prospects remain bright*, Business Standard (Sept. 12, 2013), http://www.business-standard.com/article/markets/sun-pharma-s-prospects-remain-bright-113091200894_1.html.

[25] Credit Suisse, *Sun Pharma: Ten lesser known facts about Sun Pharma* (Oct. 8, 2014), https://doc.research-and-analytics.csfb.com/docView?language=ENG&source=ulg&format=PDF&document_id=1039368961&serialid=1wxTQyF3lL1Tf9kOXZwe2hjSperihBg9iTMf%2FADhX20%3D.

level, and tripling at the retail pharmacy level.[26] Indeed, patients who had paid pennies per tablet for digoxin are now paying as much as $1.60 per tablet in certain areas.[27]

72. *Bloomberg BusinessWeek* reported that there was a ten-fold increase in the price of a three-month supply of digoxin tablets at one pharmacy in Sioux City, Iowa. Another pharmacist, speaking more generally about the sudden rise in the prices of generic drugs, stated that while sharp price increases "happened with the occasional individual drug, when there is a shortage or something," he has "never seen it like this—with a whole range of medications where the price spikes overnight."[28]

73. More recently, another pharmacist testifying before Congress stated that the price of a patient's digoxin prescription "jumped from about $15 for 90 days' supply, to about $120 for 90 days' supply."[29]

74. The timing of these exorbitant price increases was no accident. The market was essentially down to two players, thus allowing the opportunity for Defendants to hatch their conspiracy to raise the prices of digoxin tablets. This opportunism was reflected in the words of Lannett's CEO, Arthur Bedrosian, who boasted to investors that "[***w***]***e are an opportunistic company. We see opportunities to raise prices***."[30] Further, in a fourth quarter earnings call in 2013, Bedrosian called on his competitors and fellow co-conspirators to do the same, acknowledging the ease with which a reduced competitive market encouraged collective pricing:

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[26] *See* Elizabeth Rosenthal, *Rapid Price Increases for Some Generic Drugs Catch Users by Surprise*, N.Y. Times (July 8, 2014), http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html?_r=0.

[27] *Id.*

[28] Alan Katz, *Surprise! Generic-Drug Prices Spike*, Bloomberg BusinessWeek (Dec. 12, 2013), http://www.businessweek.com/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise.

[29] Testimony of Rob Frankil before Senate Subcommittee on Primary Health and Aging (Nov. 20, 2014).

[30] Kevin Dobbs, *Lannett Co. Gets Growth Rx In Generic Drug Group*, Investor's Business Daily (Oct. 27, 2014), http://news.investors.com/business-the-new-america/102714-723613-lannett-company-sees-room-to-grow-in-hot-generic-drugs-group.htm?p=2 (emphasis added).

> **I am finding a climate out there has been changed dramatically and I see more price increases coming from our competing—competitors than I've seen in the past. And we're going to continue to lead. We have more price increases planned for this year . . . . And hopefully, our competitors follow suit. . . . [O]ur plan is to raise prices on any product that we think we can or we haven't raised a price**.[31]

75. Lannett and Impax saw an opportunity to drive digoxin tablet prices up, but each could not do so unilaterally because if only one did, it risked being undercut by the other. As a result, Lannett and Impax agreed to increase their prices in unison.

76. However, an agreement between just Lannett and Impax would not be sufficient to sustain their supracompetitive pricing of digoxin tablets for long. Both knew that other generic drug manufacturers, such as Par and West-Ward, would join (in the case of Par) or rejoin (in the case of West-Ward) the digoxin tablet market upon seeing the new high prices. Absent inviting these potential competitors into their price-fixing conspiracy, Lannett and Impax would have competed against them by dropping their supracompetitive prices to more competitive levels.

77. Par joined Lannett and Impax's price-fixing conspiracy in or around the time Par launched its authorized generic version of Lanoxin. Indeed, less than one month after Par announced its launch of its authorized generic Lanoxin, Lannett's Bedrosian stated in a February 2014 analyst call that Lannett did not see Par "***discounting to our*** [Lannett's] ***price*** . . . . We've seen their prices discounted to the brand, of course, ***but we're not troubled by their pricing in the marketplace. Not at all***."[32] The reason that Bedrosian was "not troubled" by Par's pricing was because Par priced its digoxin tablets at levels comparable to that of Lannett and Impax.

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[31] Arthur P. Bedrosian, CEO Lannett Co., Lannett Management Discusses Q4 2013 Results – Earnings Call Transcript, Seeking Alpha (Sept. 10, 2013), http://seekingalpha.com/article/1685792-lannett-management-discusses-q4-2013-results-earnings-call-transcript?part=single (emphasis added).

[32] Arthur P. Bedrosian, CEO Lannett Co., Lannett Management Discusses Q2 2014 Results – Earnings Call Transcript, Seeking Alpha (Feb. 6, 2014), http://seekingalpha.com/article/2002271-lannett-management-discusses-q2-2014-results-earnings-call-transcript?all=true&find=par%2Bpharmaceuticals%2Bdigoxin (emphasis added).

78. West-Ward, upon the reopening of its Eatontown facility in 2013, also joined Lannett and Impax's price-fixing conspiracy. On joining the conspiracy, West-Ward dutifully priced its "competing" digoxin tablets at levels that matched Lannett, Impax, and later, Par.

79. Defendants' conspiracy to fix prices and allocate markets and customers resulted in an ***over 800% increase*** in the prices of digoxin tablets. This price hike affected digoxin tablets purchasers at all levels of the distribution chain. For example, the striking jump in prices for Impax's and Lannett's digoxin tablets can be seen in the following tables:

WAC for Impax's Digoxin (0.125 mg tablets, 1 bottle, 100 pills)[33]

WAC	
Price	**Effective**
$14.21	05/26/2010
$118.50	10/22/2013

WAC for Lannett's Digoxin (0.125 mg tablets, 1 bottle, 100 pills)[34]

WAC	
Price	**Effective**
$14.21	08/19/2002
$17.45	04/01/2009
$118.50	10/16/2013

80. As these tables show, WAC for Lannett's 0.125 mg digoxin tablets increased from $14.21 per 100 tablet bottle in August 2002 to only $17.45 per 100 tablet bottle in April 2009—only a 22% increase over a period of nearly seven years. By contrast, in a little over four years, prices for that same bottle jumped from $17.45 in April 2009 to $118.50 in October 2013—***an increase of 579%***. A similarly large price increase was observed with respect to

[33] Oppenheimer Equity Research, Lannett Company, Inc., at 2 (Feb. 7, 2014).

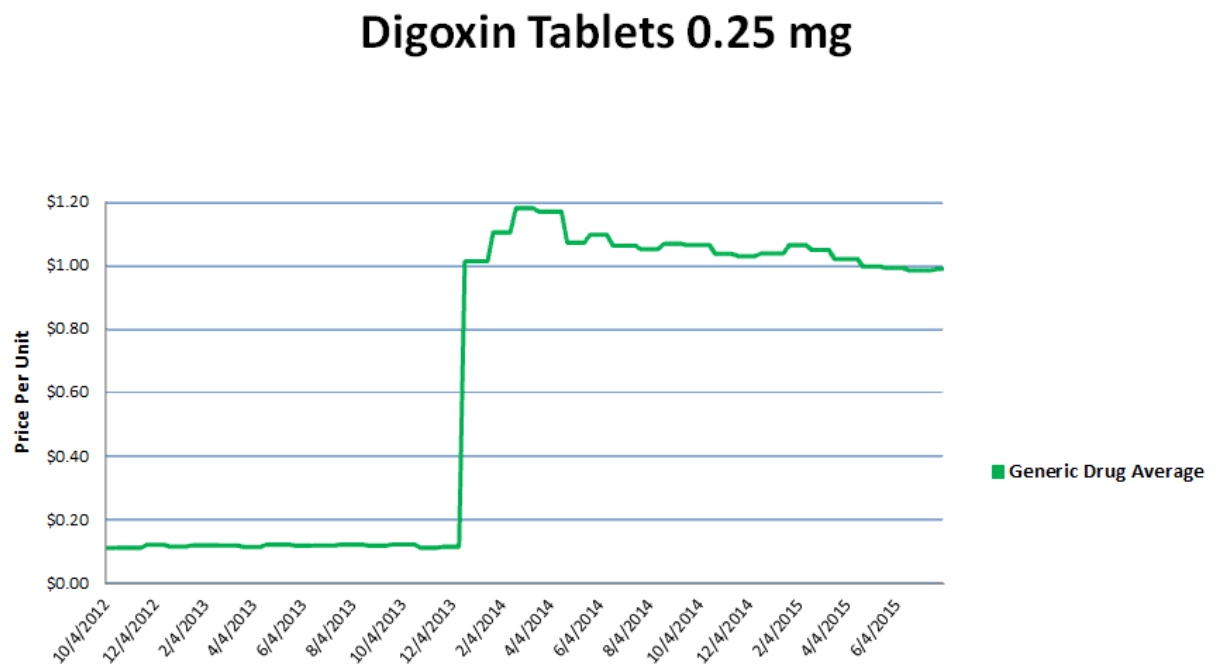
[34] *Id.*

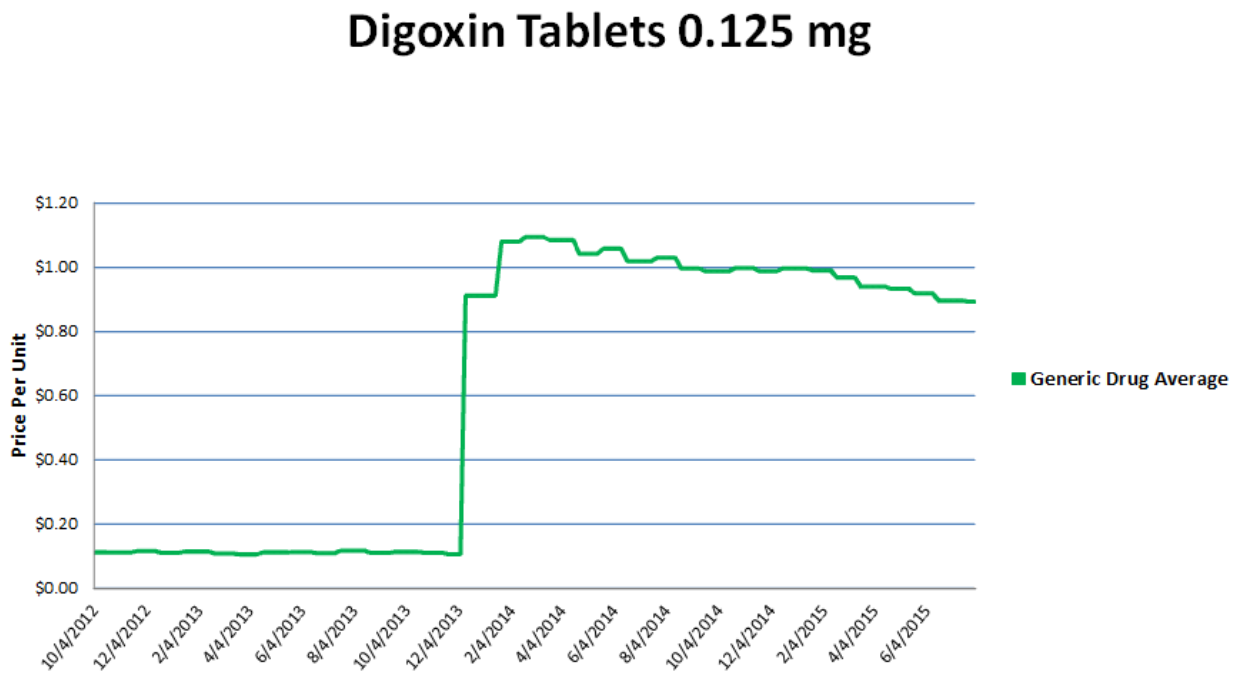
Impax's version of digoxin tablets, with prices going from $14.21 per bottle in May 2010 to $118.50 per bottle in October 2013—***an increase of around 734%*** in a little over three years.

81. Further evidence of these staggering price increases was presented by Dr. Schondelmeyer at a November 2014 congressional hearing. He testified that generic digoxin prices were generally stable prior to October 2013. Dr. Schondelmeyer tracked Lannett's AWP, WAC, and retail prices for 0.25 mg digoxin tablets. Dr. Schondelmeyer found that Lannett's AWP for digoxin tablets, 0.25 mg held steady at around $0.20 per day from January 2005 to the beginning of October 2013. Similarly, WAC held steady at around $0.10 per day during that same period. However, in October 2013, AWP skyrocketed to $1.90 per day—an increase of nearly ***850%***—and WAC increased to $1.00—an increase of nearly ***900%***.[35]

82. Similar to doxycycline, Plaintiff also analyzed several sources of data for digoxin tablets (some of which is subject to a non-disclosure agreement), including CMS's NADAC data. The CMS data, depicted below, shows that the price hikes for digoxin tablets were also generally in lock-step and industry-wide. The charts below show the average price per unit (tablet) of generic digoxin tablets in between October 2012 and July 2015:

[35] Statement of Stephen W. Schondelmeyer, BS Pharm, Senate Hearing on "Why Are Some Generic Drugs Skyrocketing in Price?" at App'x B.8.





83. The data show that prices for digoxin tablets, 0.25 mg, have ***increased 800%***, from an average market price of $0.11 per tablet as of October 4, 2012 to $0.99 per tablet as of July 22, 2015. Similarly staggering prices increases were found for the 0.125 mg tablets, which

went from $0.11 per tablet as of October 4, 2012 to $0.89 per tablet as of July 22, 2015—***a nearly 710% increase*** in price per tablet.

84. Similar to doxycycline, these price increases for digoxin tablets were not the result of a competitive market. Instead, these supracompetitive prices were the product of a conspiracy between Defendants to raise, maintain, and stabilize the prices of doxycycline to purchasers in the United States.

85. Defendants have reaped substantial revenues from their collusive practices regarding the sale of digoxin tablets. According to a fourth quarter 2014 earnings call with Lannett's investors, Lannett CEO Bedrosian stated that "[f]or the fiscal 2014 fourth quarter, we [Lannett] ***recorded the highest net sales, gross margin and net income in our company's 72-year history***."[36] Compared with fourth quarter 2013 results, Bedrosian stated that "net sales doubled to $81 million, gross margin more than tripled, and net income grew 6-fold to $24 million . . . ."[37]

86. Impax similarly experienced a substantial growth in revenues due to its inflated digoxin tablet prices. Fredrick Wilkinson, Impax's President and CEO, stated during a third quarter 2014 earnings call with investors that "[o]ur [Impax's] second quarter revenues increased 19% to $158 million."[38] The generics division of Impax, Global Pharmaceuticals, grew at a rate that outpaced the company as a whole, increasing 26%, or $30 million, over the third quarter of

[36] Lannett Co., Inc., Q4 2014 Earnings Call (Aug. 27, 2014), http://seekingalpha.com/article/2455895-lannetts-lci-ceo-arthur-bedrosian-on-q4-2014-results-earnings-call-transcript?part=single.

[37] *Id.*

[38] Impax Laboratories Inc., Q3 2014 Earnings Call (Nov. 4, 2014), http://seekingalpha.com/article/2638955-impax-laboratories-ipxl-ceo-frederick-wilkinson-on-q3-2014-results-earnings-call-transcript?part=single.

2013. According to Bryan Reasons, Impax's CFO, this growth was attributable, in part, "***from higher sales of Digoxin*** and Oxymorphone."[39]

87. One analyst report for Impax projected an over ***six-fold increase*** in revenues attributable to digoxin tablet sales between 2013 and 2014, rising from $5,622,000 to $35,526,000.[40] Another report found that first quarter 2014 sales for Impax's digoxin tablets grew by ***over 1,200%***, and contributed almost 10% of Impax's total revenues.[41]

C. Defendants' Conspiratorial Conduct to Fix Prices and Allocate Customers and Markets for Generic Doxycycline and Digoxin Tablets

88. There is no market-based reason for the increase in digoxin tablet or doxycycline prices, such as increased costs in connection with the production of these products.

89. Rather, Defendants sustained these supracompetitive profits by conspiring to fix, raise, maintain, and stabilize the prices of doxycycline and digoxin tablets, and allocate markets and customers for those products. The price increases were the product of Defendants' shared desire to extract monopoly rents from captive drug purchasers.

90. Defendants accomplished their price-fixing and market and customer allocation conspiracy through, among other things, meetings and the exchange of confidential information regarding pricing, costs, manufacturing, and supply issues.

91. The purpose of these secret, conspiratorial meetings, discussions, and communications was to ensure that all Defendants agreed to participate in, implement, and maintain an unlawful price-fixing and market and customer allocation scheme.

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[39] *Id* (emphasis added).

[40] The Buckingham Research Group, Impax Laboratories Inc. (IPXL) (May 7, 2014) at 4.

[41] Wells Fargo Securities, LLC, Impax Laboratories, Inc. (Aug. 7, 2014) at 7.

92. As a result of their unlawful agreements, Defendants fixed the price for doxycycline during the period October 1, 2012 through the present and for digoxin tablets during the period October 1, 2013 through the present.

93. In formulating and effectuating their conspiracy, Defendants engaged in numerous anticompetitive activities, including, among other things:

(a) Attending joint meetings or otherwise engaging in joint discussions in the United States by telephone, facsimile, and electronic mail regarding the sale of doxycycline and digoxin tablets;

(b) Agreeing to charge prices for doxycycline and digoxin tablets at specified levels, and otherwise fix, increase, maintain, and stabilize the prices and supply of doxycycline and digoxin tablets sold to purchasers in the United States;

(c) Selling doxycycline and digoxin tablets to customers in the United States at collusive and non-competitive prices pursuant to the agreements reached;

(d) Accepting payments for doxycycline and digoxin tablets sold in the United States at collusive and non-competitive prices;

(e) Communicating with one another to discuss the prices, customers, markets, supply and manufacturing issues, and price levels of doxycycline and digoxin tablets sold in the United States;

(f) Authorizing or consenting to the participation of employees in the conspiracy; and

(g) Concealing the conspiracy and conspiratorial contacts through various means.

94. As a result of Defendants' unlawful agreement to restrain trade, Plaintiff and members of the Classes were injured because they paid, and continue to pay, supracompetitive prices for doxycycline and digoxin tablets sold in the United States.

GENERIC MARKETS FOR DOXYCYCLINE AND DIGOXIN ARE SUSCEPTIBLE TO A PRICE FIXING CONSPIRACY

A. Factors Supporting the Existence of a Conspiracy in the Markets for Doxycycline and Digoxin Tablets

95. The structure and other characteristics of the markets for doxycycline and digoxin tablets make them conducive to collusion and price-fixing. Specifically, during the Doxycycline and Digoxin Class Periods, the markets for digoxin tablets and doxycycline exhibited: (1) high barriers to entry; (2) inelasticity of demand; (3) a high degree of commoditization; (4) a high degree of concentration; and (5) opportunities to conspire.

1. There Are High Barriers to Entry in the Markets for Doxycycline and Digoxin Tablets

96. A collusive arrangement that raises product prices above competitive levels would, under basic economic principles, attract new entrants seeking to benefit from the supra-competitive pricing. When, however, there are significant barriers to entry, new entrants are much less likely to enter the market. Thus, barriers to entry help facilitate the formation and maintenance of a cartel.

97. The markets for doxycycline and digoxin tablets have high barriers to entry.

98. Even though doxycycline and digoxin tablets are not protected by any patents, regulatory hurdles and the costs of doing business make market entry difficult, time consuming, and expensive. Any generic drug manufacturer seeking to enter the markets for digoxin tablets or doxycycline must file an ANDA and receive FDA approval.

99. To file an ANDA, the generic manufacturer must show that the generic product is bioequivalent to its branded counterpart and invest considerable resources in the development of production lines capable of making the drug. Historically, the cost of filing an ANDA is about $1 million.[42] A generic manufacturer's production facilities must also meet CGMP standards, which increase the costs of production.

100. This is particularly true for a drug like digoxin, which is known to be difficult to produce in low dosage forms. Indeed, this is evidenced by the fact that Mylan, Hikma, and Sun have all experienced manufacturing difficulties that led to recalls, facility shutdowns, and, in the cases of Mylan and Sun, market exit (at least temporarily, for Mylan). As a result, new entrants, even those with well-established manufacturing facilities, still face significant start-up and compliance costs associated with digoxin tablet manufacturing.

101. Moreover, a generic manufacturer that cannot produce the Active Pharmaceutical Ingredient ("API") for digoxin tablets or doxycycline must have a reliable source of API.

102. Prospective generic manufacturers must also be able to satisfy FDA regulations and guidance governing bioequivalence and bioavailability of their doxycycline and digoxin products. This requires showing that the proposed generic doxycycline and digoxin products have, among other things, the same therapeutic qualities and absorption profiles as their branded counterparts.

103. The failure to meet all FDA requirements concerning manufacturing, testing, and labeling of doxycycline and digoxin tablets products will result in the FDA delaying (or denying) approval of an ANDA. These delays can last for months or even years.

[42] Testimony of Dr. Scott Gottlieb, Hearing on "Why Are Some Generic Drugs Skyrocketing in Price?" (Nov. 20, 2014), at 7.

104. Even if a non-conspiring generic manufacturer were to see an opportunity to compete on price regarding doxycycline and digoxin, due to the fact that the FDA's review of ANDAs is currently significantly "backlog[ged]", any potential entrant would necessarily be delayed for years.[43]

2. Inelasticity of Demand for Doxycycline and Digoxin Tablets

105. "Elasticity" is a term used to describe the sensitivity of supply and demand to changes in one or the other. For example, demand is said to be "inelastic" if an increase in the price of a product results in only a small decline, if any, in the quantity sold of that product. In other words, customers have nowhere to turn for alternative, cheaper products of similar quality, and so continue to purchase the product despite the price increase.

106. For a cartel to profit from raising prices above competitive levels, demand must be relatively inelastic at competitive prices. Otherwise, increased prices would result in declining sales, revenues, and profits as customers purchased substitute products or declined to buy altogether. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue.

107. Demand for doxycycline and digoxin tablets are highly inelastic because both are unique products: digoxin is a unique compound that is used for the treatment of atrial fibrillation and heart failure; doxycycline is similarly unique in that it is used to treat a broad spectrum of bacterial infections. Both doxycycline and digoxin are considered "essential medicines" by the World Health Organization because of their widespread use.

[43] *Id.* at 7.

108. In the case of digoxin, while other medications exist for the treatment of atrial fibrillation, many doctors, particularly geriatricians and general practitioners, see digoxin as the primary medication for the treatment of this condition.

109. Furthermore, other atrial fibrillation drugs have different mechanisms for treating atrial fibrillation that can be used as complements to, rather than substitutes for, digoxin. For example, sodium and potassium channel blockers like flecainide, propafenone, or sotalol, are used for controlling heart *rhythm* in patients with atrial fibrillation, while digoxin is used to control heart *rates* in patients with atrial fibrillation.

110. Even other heart rate controlling medications, such as beta blockers, are not ready substitutes for digoxin tablets because they have different chemical and pharmacokinetic properties that may not make them suitable treatment options under many circumstances. One study published in the *Journal of the American College of Cardiology* found "***that digoxin is still a first-line alternative*** to control ventricular rate in patients with atrial fibrillation, particularly in cases with congestive heart failure and left ventricular systolic dysfunction."[44]

111. In the case of doxycycline, other antibiotics—even other tetracycline antibiotics—are not substitutes for doxycycline. Medical professionals consider doxycycline a "workhorse" drug—the standard prescription for the treatment of a variety of bacterial infections, including bacterial pneumonia, acne, chlamydia, Lyme disease, cholera, and syphilis.[45]

112. Other tetracyclines, such as chlortetracycline and oxytetracycline, are short acting antibiotics, with half-lives of between six and eight hours—meaning that half of these drugs'

[44] Henrique H. Veloso & Angelo A.V. de Paola, *Beta-Blockers Versus Digoxin to Control Ventricular Rate During Atrial Fibrillation*, 45 J. Am. Coll. Cardiology 1905, 1906 (June 2005), http://content.onlinejacc.org/article.aspx?articleid=1136643.

[45] Dr. Jeremy A. Greene, *Drug Bust*, Slate (Nov. 20, 2014), http://www.slate.com/articles/business/moneybox/2014/11/generic_drug_prices_why_their_prices_are_suddenly_surging.html.

pharmacological benefits have been used within that period. By contrast, doxycycline has a half-life of 16 hours, *i.e.*, double that of either chlortetracycline or oxytetracycline. Further, even as compared to other longer-acting tetracyclines, such as minocycline, studies have found that doxycycline has resulted in fewer adverse events in patients, thereby making it the standard choice among physicians for the bacterial infections listed above.[46]

113. In addition, branded versions of digoxin tablets or doxycycline do not serve as economic substitutes for generic versions of these compounds because branded products generally maintain substantial price premium over their generic counterparts, making them inapt substitutes even when generic prices soar. For example, WAC pricing for Lanoxin (the branded version of digoxin tablets) was $240.00 per 100 tablet bottle in August 2013, which was over double both Impax's and Lannett's WAC prices for digoxin tablets around that time, which was $118.50 per 100 tablet bottle for Impax's and Lannett's digoxin tablets.[47]

114. Thus, purchasers of doxycycline and digoxin tablets are held captive to the supracompetitive prices that resulted from Defendants' conspiracy to fix prices and allocate markets and customers.

3. Doxycycline and Digoxin Tablets Are Commodity Products

115. When products are subject to commoditization, producers of those products are usually forced to compete on price, as opposed to other factors, such as quality and ancillary services. When price becomes a significant factor in driving demand for a product, producers of a commoditized product have an easier time colluding on price than other non-price factors because price-based collusion is much easier to implement and monitor.

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[46] *See* Kelly Smith & James J. Leyden, *Safety of doxycycline and minocycline: A systematic review*, 27 Clinical Therapeutics 1329 (Sept. 2005), http://www.ncbi.nlm.nih.gov/pubmed/16291409.

[47] Oppenheimer Equity Research, Lannett Company, Inc. (Feb. 7, 2014) at 2.

116. Generic drugs of the same chemical composition are effectively commodity products because the primary mechanism through which they compete is price. Because the FDA, when approving an ANDA, is required to determine whether a generic drug product is bioequivalent to the brand's NDA, an AB-rating permits a pharmacist to substitute an AB-rated generic for its branded counterpart, as well as to substitute one AB-rated generic for another AB-rated generic for the same branded product.

117. Because Defendants' digoxin tablets are AB-rated generics of Lanoxin, pharmacists are permitted to substitute them for Lanoxin. Similarly, Defendants' doxycycline tablets are AB-rated generics of their branded counterparts, enabling pharmacists to substitute them for branded products.

118. Moreover, because generic manufacturers generally spend little effort advertising or detailing their generic compounds (*i.e.*, the practice of providing promotional materials and free samples to physicians), the primary means for one generic manufacturer to differentiate its product from another generic competitor's is through price reductions.[48] The need to compete on price can drive producers of commodity products to conspire—as they did here—to fix prices.

4. The Market for Generic Doxycycline and Digoxin Tablets Is Highly Concentrated

119. A concentrated market is more susceptible to collusion and other anticompetitive practices. Both markets for doxycycline and digoxin tablets are highly concentrated. Defendants possess large market shares in their respective markets. Between October 2013 and the present, after substantial consolidation in the market, there were only a handful of manufacturers of generic digoxin tablets: Impax, Lannett, Mylan, Par, and West-Ward. Further, between October

[48] *See* Congressional Budget Office, Promotional Spending for Prescription Drugs, Economic & Budget Issues Brief (Dec. 2, 2009), at 1.

2013 and early January 2014 the market for digoxin tablets was dominated by only three competitors: Impax, Lannett, and West-Ward.

120. Similarly, although there were as many as 20 generic manufacturers producing doxycycline over the past two decades, those numbers of have steadily decreased, thereby substantially increasing the concentration in the doxycycline market.

121. By October 2012, the market for generic doxycycline was dominated by six manufacturers: Allergan, Lannett, Mylan, Par, Sun, and West-Ward. When examining the generic manufacturers of the two different forms of doxycycline (hyclate and monohydrate), concentration increases further: four produce doxycycline hyclate (Allergan, Mylan, Sun, and West-Ward); and five produce doxycycline monohydrate (Allergan, Lannett, Mylan, Par and Sun).

122. Because there were a limited number of doxycycline and digoxin manufacturers in the market, it facilitated their ability to coordinate pricing of their respective products. This concentration also made it easy for them to monitor prices in the downstream market and police deviations from agreed-upon prices.

123. As the dominant players in both the markets for doxycycline and digoxin tablets, Defendants were able to fix, raise, and maintain their prices on their doxycycline and digoxin tablet products without competitive threats from other competing generic drug manufacturers. The overlap is striking:

	Digoxin Tablets	Doxycycline
Mylan	✓	✓
Lannett	✓	✓
Par	✓	✓
Sun	✓	✓
West-Ward	✓	✓
Allergan		✓
Impax	✓	

5. Defendants Had Opportunities to Conspire

124. In order to be sustained, conspiracies require periodic communications between its members to ensure that all are adhering to the collective scheme.

125. Defendants were members of trade associations, which they used to facilitate their conspiratorial communications and implement their price-fixing scheme. One such trade association is the Generic Pharmaceutical Association ("GPhA"), which is the largest association of generic pharmaceutical manufacturers.

126. Current "Regular Members" of the GPhA include Defendants Impax, Mylan, Par, Sun, and West-Ward. Regular Members "are corporations, partnerships or other legal entities whose primary U.S. business derives the majority of its revenues from sales of (1) finished dose drugs approved via ANDAs; (2) products sold as authorized generic drugs; (3) biosimilar/ biogeneric products; or (4) DESI products."[49] Several of Defendants' high-ranking officers serve on GPhA's Board of Directors, including Mylan's Heather Bresch, Impax's Marcy MacDonald,

[49] GPhA, Membership, http://www.gphaonline.org/about/membership.

Par's Tony Pera, and Sun's Jim Kedrowski. Ms. Bresch serves as the GPhA's current Chairperson.

127. Representatives from Defendants attended meetings held by GPhA. The following table lists some of the GPhA meetings attended by Defendants' employees:

Meeting	Meeting Date and Location	Attendees
2012 GPhA Annual Meeting	February 22-24, 2012, Orlando, Florida	Watson (now part of Allergan), Mylan, Par
2012 GPhA Fall Technical Conference	October 1-3, 2012, Bethesda, Maryland	Actavis (now Allergan), Lannett, Impax, Mylan, Sun
2013 GPhA Annual Meeting	February 20-22, 2013, Orlando, Florida	Actavis (now Allergan), Impax, Mylan, Par
2013 GPhA Fall Technical Conference	October 28-30, 2013, Bethesda, Maryland	Actavis (now Allergan), Impax, Lannett, Mylan, Par, Sun
2014 GPhA Annual Meeting	February 19-21, 2014, Orlando, Florida	Actavis (now Allergan), Impax, Mylan, Par, Sun

128. Upon information and belief, Defendants' employees discussed their anticompetitive scheme to raise, maintain, and stabilize the prices of doxycycline and digoxin tablets, and how to allocate markets and customers, at these meetings, among others.

GOVERNMENT INVESTIGATIONS INTO GENERIC DRUG MARKET

A. Congressional Investigations into Generic Drug Pricing

129. As news reports have proliferated with respect to the dramatic rise in price of certain generic drugs, members of Congress have expressed a growing interest in what is driving these price hikes. On October 2, 2014, Representative Elijah E. Cummings, the Ranking Member of the House Committee on Oversight and Government Reform, and Senator Bernard Sanders, Chairman of the Subcommittee on Primary Health and Aging, Senate Committee on Health,

Education, Labor and Pensions, "sent letters to 14 drug manufacturers requesting information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses."[50]

130. These letters were delivered to Defendants' Presidents and CEOs and others—including Apotex Corp., Endo Pharmaceuticals plc, Heritage Pharmaceuticals Inc., Dr. Reddy's Laboratories Ltd., Marathon Pharmaceuticals, LLC, Teva Pharmaceuticals Industries Ltd., and Zydus Pharmaceuticals USA Inc.—seeking information about the pricing of digoxin tablets, doxycycline, albuterol sulfate, glycopyrrolate, divalproex sodium ER, pravastatin sodium, neostigimine methylsulfate, benazepril/hydrochlorothiazide, Isuprel® (isoproterenol hydrochloride), and Nitropress® (nitroprusside):

GENERIC MANUFACTURER	GENERIC DRUGS
Actavis plc	**doxycycline**
Impax Laboratories, Inc.	**digoxin**
The Lannett Company	**doxycycline; digoxin**
Mylan Inc.	**doxycycline**; albuterol sulfate; benazepril/hydroclorothiazide; divalproex sodium ER; pravastatin sodium
Par Pharmaceutical Companies Inc.	**doxycycline**; divalproex sodium ER; glycopyrrolate; pravastatin sodium
Sun Pharmaceutical Industries, Inc.	**doxycycline**; albuterol sulfate; divalproex sodium ER
West-Ward Pharmaceuticals Corp**.**	**doxycycline**; **digoxin**; glycopyrrolate; neostigmine methylsulfate

[50] Ranking Members Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs, http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file.

131. Each letter stated:

> This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community of Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients[']and pharmacies[']ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays," and "84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a 'very significant' impact on their ability to remain in business to continue serving patients."[51]

132. Further, Senator Sanders and Representative Cummings published a table in connection with their letters, demonstrating the massive price increases that both doxycycline and digoxin tablets have experienced over the past several years:

Drug	Use	Average Market Price Oct. 2013	Average Market Price April 2014	Average Percentage Increase
Doxycycline Hyclate (bottle of 500, 100 mg tablets)	antibiotic used to treat a variety of infections	$20	$1,849	8,281%

Drug	Use	Average Market Price Oct. 2012	Average Market Price June 2014	Average Percentage Increase
Digoxin (single tablet, 250 mcg)	used to treat irregular heartbeats and heart failure	$0.11	$1.10	884%

133. In addition to sending letters to the generic drug manufacturers listed above, Senator Sanders and Representative Cummings wrote a joint letter to Sylvia Burwell, the

[51] *See, e.g.*, Letter from Sen. Bernard Sanders & Rep. Elijah E. Cummings to Arthur P. Bedrosian (Oct. 2, 2014), http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file (citing Letter from B. Douglas Hoey to Sen. Tom Harkin, et al. (Jan. 8, 2014), https://www.ncpanet.org/pdf/leg/jan14/letter-generic-spikes.pdf)).

Department of Health and Human Services Secretary, stating that "[t]he federal government must act immediately and aggressively to address the increasing costs of these drugs."[52]

134. The Senate Subcommittee on Primary Health and Aging held a hearing on November 20, 2014. Although the Presidents and CEOs of Lannett, Teva, and Marathon Pharmaceuticals were scheduled to attend the hearing, none appeared. Many panelists agreed that reduced competition across various generic drugs, including doxycycline and digoxin, has contributed to the price hikes observed in the overall market. For example, Aaron S. Kesselheim, Associate Professor of Medicine at Harvard Medical School, testified that "the number of manufacturers producing oral digoxin tablets . . . fell from 8 to 3 companies from 2002 to 2013; during that time, the price of digoxin reportedly rose by 637%.[53]

135. Subsequent congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging's December 9, 2015 hearing, Erin D. Fox, PharmD Director of the Drug Information Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating that "[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage."[54]

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[52] Congressional Panel to Probe Generic Drug Price Hikes (Nov. 11, 2014), http://www.sanders.senate.gov/newsroom/press-releases/congressional-panel-to-probe-generic-drug-price-hikes.

[53] Testimony of Dr. Aaron S. Kesselheim, Assoc. Professor of Medicine Harvard Med. Schl., Hearing on "Why are some drugs skyrocketing in price?" (Nov. 20, 2014), at 5, http://www.help.senate.gov/imo/media/doc/Kesselheim.pdf.

[54] Statement of Erin R. Fox, PharmD Director, Drug Information Service, Hearing on "Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines" (Dec. 9, 2015), at 7, http://www.aging.senate.gov/imo/media/doc/SCA_Fox_12_9_15.pdf.

136. On February 24, 2015, Senator Sanders and Representative Cummings wrote to Daniel R. Levinson, the Inspector General of the Department of Health and Human Services, imploring the department to "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs."[55] On April 13, 2015, Inspector General Levinson responded to Senator Sanders and Representative Cummings' letter, stating that his office planned "to update our previous review of generic drug price increases under the Medicaid drug rebate program."[56]

B. Federal and State Antitrust Investigations into Defendants' Generic Drug Pricing

137. Generic pricing patterns have also captured the attention of federal and state enforcement authorities in the United States. Many Defendants have received requests for information concerning their pricing of generic drugs, including doxycycline and digoxin, as well as their communications with their competitors for those drugs.

138. ***Lannett.*** In July 2014, both Lannett and Impax revealed in SEC filings that they had received subpoenas from the CTAG in connection with its investigation into whether "anyone engaged in a contract, combination or conspiracy in restraint of trade or commerce which has the effect of (i) fixing, maintaining or controlling prices of digoxin or (ii) allocating and dividing customers or territories relating to the sale of digoxin in violation of Connecticut antitrust law."[57]

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[55] Letter from Hon. Bernard Sanders and Elijah Cummings to Hon. Daniel Levinson (Feb. 24, 2015), http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

[56] Letter from Hon. Daniel Levinson to Hon. Bernard Sanders (Apr. 13, 2015), http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

[57] Impax Laboratories (IPXL) Receives Subpoena from Connecticut AG, http://www.streetinsider.com/Corporate+News/Impax+Laboratories+(IPXL)+Receives+Subpoena+from+Connecticut+AG/9662945.html; Lannett Receive Inquiry from Connecticut Attorney General, http://finance.yahoo.com/news/lannett-receives-inquiry-connecticut-attorney-153300612.html.

139. The information and documents sought by the CTAG included: (1) the identification of "all persons at Lannett with any supervisory, executive or other significant non-ministerial responsibility related to the pricing or sale of Digoxin"; (2) the identification and production of "all documents or communications referring or relating to any decision(s), by you or any other company, to increase the price of Digoxin"; (3) the production of "[a]ll marketing plans, strategic plans or any other documents relating to the development, manufacture and commercialization of Digoxin"; and (4) the identification and production of "written compliance policy directed to the antitrust laws."

140. Five months later, on November 10, 2014, Lannett disclosed in an SEC filing that a senior sales and marketing executive was served with a DOJ grand jury subpoena "relating to a federal investigation of the generic industry into possible violations of anti-trust laws."[58]

141. On December 5, 2014, Lannett disclosed in a Form 8-K that it received another "grand jury subpoena related to the continuing federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act."[59] Lannett further disclosed that the "subpoena requests corporate documents from the Company relating to corporate, financial, and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale, or pricing of certain products."[60] In a 2015 SEC filing, Lannett further disclosed that the federal subpoenas requested information and documents for the period 2005 through the dates the subpoenas were issued.

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[58] Ed Silverman, *Justice Department Probes Generic Companies After Price Hike Reports*, Wall. St. J. (Nov. 10, 2014).

[59] Lannett Form 8-K (Dec. 5, 2014), http://www.sec.gov/Archives/edgar/data/57725/000110465914085406/a14-25827_18k.htm.

[60] *Id.*

142. ***Impax.*** Impax disclosed that it also received a federal grand jury subpoena requesting testimony and documents about "any communication or correspondence with any competitor about the sale of generic drugs."[61] The scope of the subpoenas was not limited to a particular drug or a particular timeframe. The grand jury investigating the matter is empaneled in the Eastern District of Pennsylvania.

143. Later, Impax disclosed that on March 13, 2015, "the Company received a grand jury subpoena from the Justice Department requesting the production of information and documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular the Justice Department's investigation currently focuses on four generic medications: digoxin tablets, terbualine sulfate tablets, prilocaine/lidocaine cream, and calcipotriene topical solution."[62]

144. ***Par.*** The federal grand jury's probe continues to expand. In a SEC Form 10-K for 2014, Par disclosed that it had received a subpoena from DOJ "requesting documents related to communications with competitors regarding our authorized generic version of Covis's Lanoxin® (digoxin) oral tablets and our generic doxycycline products."[63] Moreover, in that same filing Par revealed that the CTAG served a subpoena on Par on August 6, 2014 "requesting documents related to our agreement with Covis Pharma S.a.r.l. to distribute an authorized generic version of Covis's Lanoxin® (digoxin) oral tablets."[64] Par stated that it completed its response on October 28, 2014.

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[61] *Id.*

[62] Impax, SEC 2015 Form 10-K, at F-53.

[63] Par Pharmaceuticals Companies, Inc., SEC 2014 Form 10-K, at 37.

[64] *Id.*

145. ***Allergan.*** Allergan also disclosed in public filings that they received subpoenas from DOJ. Allergan reported that on June 25, 2015, Actavis received a subpoena from DOJ "seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with competitors about such products."[65]

146. ***Mylan.*** Mylan similarly disclosed in a 2016 SEC filing that it received a subpoena from DOJ "seeking information relating to the marketing, pricing, and sale of our generic Doxycycline products and any communications with competitors about such products."[66] Mylan received a similar subpoena from the CTAG, seeking "information relating to the marketing, pricing and sale of certain of the Company's generic products (including Doxycycline) and communications with competitors about such products."[67]

147. Further, according to public reports, DOJ's criminal probe is focusing on trade associations, including GPhA, because these trade associations may have been used by Defendants' sales representatives to coordinate and implement their anticompetitive scheme. Certain of Defendants' representatives held senior positions at the GPhA, including Mylan's Heather Bresch, Impax's Marcy MacDonald, Par's Tony Pera, and Sun's Jim Kedrowski. Upon information and belief, representatives from Defendants attended meetings held by GPhA and discussed their anticompetitive schemes to raise, maintain, and stabilize the prices of doxycycline and digoxin tablets.

ANTITRUST IMPACT

148. During the relevant period, Plaintiff and Class Members purchased substantial amounts of doxycycline and digoxin tablets indirectly from Defendants. As a result of

[65] Allergan, SEC 2015 Form 10-K, at F-106.
[66] Mylan, SEC 2015 Form 10-K, at 160.
[67] *Id.*

Defendants' illegal conduct, these purchasers have paid, and continue to pay, artificially inflated prices for doxycycline and digoxin tablets. The prices paid were substantially higher than the prices that Plaintiff and Class Members would have paid absent the illegal conduct alleged in this Complaint.

149. As a consequence, purchasers of doxycycline and digoxin tablets have sustained substantial losses and damage to their business and property in the form of overcharges—and their losses continue to date. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

150. Defendants' efforts to restrain competition in the markets for doxycycline and digoxin tablets have substantially affected interstate commerce—and continue to do so.

151. At all material times, Defendants manufactured, promoted, distributed, and sold substantial amounts of doxycycline and digoxin tablets in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase because, among other things, consumers and third-party payors within each state were forced to pay supracompetitive prices for doxycycline and digoxin tablets.

152. At all times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of doxycycline and digoxin tablets.

153. Economists recognize that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive

price at the top.[68] He also says that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."[69]

154. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of doxycycline and digoxin tablets to Plaintiff and Class Members.

155. Defendants' anticompetitive conduct enabled Defendants to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent Defendants' unlawful actions.

156. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

157. The inflated prices that Plaintiff and Class Members have paid for doxycycline and digoxin tablets, and continue to pay, are traceable to and the foreseeable result of, the overcharges by Defendants.

CLASS ALLEGATIONS

158. Plaintiff brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(2), on behalf of itself and a nationwide class of similarly situated individuals seeking injunctive and equitable relief:

> **The Injunctive Class**:
>
> All persons or entities in the United States and its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for: (i) digoxin tablets, other than for resale, for consumption by itself, its families, or its members, employees, insureds,

[68] *See* Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

[69] *Id.*

participants, or beneficiaries, from at least as early as October 1, 2013 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased; or (ii) doxycycline, in any form, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2012 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.

159. Plaintiff also brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(3), on behalf of itself and a class of similarly situated individuals seeking damages arising from Defendants' conduct as described below:

The Damages Class:

All persons or entities who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for: (i) digoxin tablets, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2013 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased; or (ii) doxycycline, in any form, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2012 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased, in any of the following states, commonwealths, and territories: Alabama, Arizona, California, Florida, Hawaii, Iowa, Kansas, Massachusetts, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia.

160. The following persons and entities are excluded from the above-described Classes:

(a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

(b) All governmental entities, except for government-funded employee benefit plans;

(c) All persons or entities who purchased doxycycline or digoxin tablets for purposes of resale or directly from Defendants or their affiliates;

(d) Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs); and

(f) The judges in this case and any members of their immediate families.

161. Members of the Classes are so numerous that joinder is impracticable. Plaintiff believes that there are thousands of members of each class.

162. Plaintiff's claims are typical of the claims of the members of the Classes. Plaintiff and members of the Classes were damaged by the same wrongful conduct by Defendants in that they paid artificially inflated prices for doxycycline and digoxin tablets as a result of Defendants' wrongful conduct—and continue to do so.

163. Plaintiff will fairly and adequately protect and represent the interests of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Classes.

164. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with experience in class action antitrust litigation involving pharmaceutical products.

165. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to each member of the Injunctive Class and Damages Class.

166. Questions of law and fact common to members of both Classes include:

(a) the identity of the participants in the conspiracy;

(b) whether Defendants conspired to fix, raise, maintain, and stabilize the prices of doxycycline and digoxin tablets;

(c) whether Defendants conspired to allocate markets or customers with respect to the market for doxycycline and digoxin tablets;

(d) whether Defendants' conduct harmed competition in the markets for doxycycline and digoxin tablets;

(e) whether Defendants' activities alleged herein have substantially affected interstate and intrastate commerce;

(f) whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Classes in the nature of overcharges;

(g) the quantum of overcharges paid by Plaintiff and members of the Classes in the aggregate; and

(h) the injunctive and other equitable relief needed to end Defendants' restraint and to restore competition in the doxycycline and digoxin tablet markets.

167. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining

redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

168. Plaintiff knows of no special difficulty to be encountered in this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of Sherman Act § 1, 15 U.S.C. § 1
(By Plaintiff and Injunctive Class Members Against All Defendants)

169. Plaintiff incorporates the preceding paragraphs by reference.

170. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme to fix, raise, maintain, and stabilize the prices of doxycycline and digoxin tablets, and allocate markets and customers for doxycycline and digoxin tablets—and continue to do so.

171. Had Defendants competed instead of conspiring to restrain trade, Plaintiff and Injunctive Class Members would have paid substantially lower prices for doxycycline and digoxin tablets.

172. Defendants intended, and accomplished, a price-fixing conspiracy and horizontal market allocation of the markets for doxycycline and digoxin tablets, which are *per se* violations of Section 1 of the Sherman Act. By their agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a result of this unreasonable restraint on competition, Plaintiff and Injunctive Class Members paid artificially inflated prices for doxycycline and digoxin tablets—and continue to do so.

173. Plaintiff and Injunctive Class Members have suffered harm, and are continuing to suffer harm, as a result of paying higher prices for doxycycline and digoxin tablets than they would have absent Defendants' anticompetitive conduct and continuing anticompetitive agreements. Plaintiff and Injunctive Class Members also face a continuing threat of injury from the unlawful conduct alleged in this Complaint.

174. Plaintiff and Injunctive Class Members have purchased substantial amounts of doxycycline and digoxin tablets indirectly from Defendants.

175. Plaintiff and Injunctive Class Members seek a declaratory judgment pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) that Defendants' conduct violates Section 1 of the Sherman Act.

176. Plaintiff and Injunctive Class Members also seek equitable and injunctive relief, including disgorgement of profits, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief to ensure that the same or similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF

State Antitrust Violations
(By Plaintiff and Damages Class Members Against All Defendants)

177. Plaintiff incorporates the preceding paragraphs by reference.

178. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme to fix, raise, maintain, and stabilize the prices of doxycycline and digoxin tablets and allocate markets and customers for doxycycline and digoxin tablets—and continue to do so.

179. Defendants' unlawful conduct harmed Plaintiff and Damages Class Members in the manner explained above.

180. Defendants' unlawful conduct covered a sufficiently substantial percentage of the relevant market to harm competition.

181. Defendants' actions constitute horizontal market allocation and price-fixing agreements between actual and potential competitors and are illegal *per se* under state antitrust laws.

182. Defendants' supracompetitive pricing constitute a continuing violation of the laws of the states listed below in that each purchase by Plaintiff or a member of the Damages Class of supracompetitively priced doxycycline and digoxin tablets caused injury to their business or property—and continue to do so.

183. Defendants' conduct violated the following state laws:

(a) Ala. Code § 6-5-60, with respect to purchases in Alabama by members of the Damages Class;

(b) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Damages Class;

(c) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Damages Class;

(d) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Damages Class;

(e) Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Damages Class;

(f) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Damages Class;

(g) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Damages Class;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Damages Class;

(i) Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Damages Class;

(j) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Damages Class;

(k) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Damages Class;

(l) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Damages Class;

(m) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class;

(n) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Damages Class;

(o) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Damages Class;

(p) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Damages Class;

(q) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Damages Class;

(r) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Damages Class;

(s) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Damages Class;

(t) Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by members of the Damages Class;

(u) R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Damages Class;

(v) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by members of the Damages Class;

(w) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Damages Class;

(x) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Damages Class;

(y) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Damages Class;

(z) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Damages Class; and

(aa) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Damages Class.

184. Plaintiff and Damages Class Members have been and continue to be injured in their business or property by Defendants' antitrust violations. Their injuries consist of: (1) being denied free and open competition between competitors in the markets for doxycycline and digoxin tablets; and (2) paying higher prices for doxycycline and digoxin tablets than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

185. Plaintiff and Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

186. Defendants are jointly and severally liable for all damages suffered by Plaintiff and Damages Class Members.

187. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the above-listed state antitrust laws.

THIRD CLAIM FOR RELIEF

Unjust Enrichment
(By Plaintiff and Damages Class Members Against All Defendants)

188. Plaintiff incorporates the preceding paragraphs by reference.

189. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

190. Defendants have benefited and continue to benefit from the overcharges on sales of doxycycline and digoxin tablets made possible by the unlawful and inequitable acts alleged in this Complaint.

191. Defendants' financial benefits are traceable to Plaintiff's and Damages Class Members' overpayments for doxycycline and digoxin tablets.

192. Plaintiff and Damages Class Members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiff and Damages Class Members.

193. It would be futile for Plaintiff and Damages Class Members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to anyone for any of the benefits they received indirectly from Plaintiff and Damages Class Members.

194. It would be futile for Plaintiff and Damages Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased doxycycline and digoxin tablets, as those intermediaries are not liable and would not compensate Plaintiff and Damages Class Members for Defendants' unlawful conduct.

195. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for doxycycline and digoxin tablets is a direct and proximate result of Defendants' unlawful practices.

196. The financial benefits Defendants derived rightfully belong to Plaintiff and Damages Class Members, who paid, and continue to pay, anticompetitive prices that inured to Defendants' benefit.

197. It would be inequitable under unjust enrichment principles under the laws of each of the states in the United States and the District of Columbia for Defendants to retain any of the overcharges Plaintiff and Damages Class Members paid for doxycycline and digoxin tablets that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

198. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the Damages Class.

199. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Damages Class Members.

200. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received that are traceable to Plaintiff and Damages Class Members.

201. Plaintiff and Damages Class Members have no adequate remedy at law.

DEMAND FOR JUDGMENT

Accordingly, Plaintiff, on its own behalf and on behalf of the proposed Classes, demands a judgment that:

A. Determines that this case may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), directs that reasonable notice of this case be given to members of the Classes under Rule 23(c)(2), and declares that Plaintiff is a proper representative of the Classes;

B. Declares that Defendants' conduct violated Section 1 of the Sherman Act, the other state statutes set forth above, and the common law of unjust enrichment;

C. Enjoins Defendants from continuing their illegal activities;

D. Enters judgment against Defendants joint and severally and in favor of Plaintiff and the Classes;

E. Grants Plaintiff and the Injunctive Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

F. Awards the Plaintiff and the Damages Class damages and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial, including interest;

G. Awards Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grants further relief as necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court deems just.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed classes, demands a trial by jury on all issues so triable.

Dated: March 25, 2016

GOLDMAN, SCARLATO & PENNY P.C.

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